Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (Last updated December 12, 2019; last reviewed December 12, 2019) (page 1 of 4)

Women should be given information about the benefits and risks of initiating an ARV regimen or making changes to an existing regimen so they can make informed decisions about their care. Patient autonomy and informed choice should be considered in all aspects of medical care, including HIV and obstetric care. This is the primary guiding principle in all the Panel's recommendations.

ART Regimen Component	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[a]	New ARV Regimen for Pregnant Women Whose Current Regimen is Not Well Tolerated and/or is Not Fully Suppressive[a]	ART for Nonpregnant Women Who Are Trying to Conceive[a,b]
INSTIs Used in combination with a dual-NRTI backbone[c]					
DTG[d]	Preferred	Continue	Preferred	Preferred	Alternative
RAL	Preferred	Continue	Preferred	Preferred	Preferred
BIC	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
EVG/c[e]	Not recommended	Consider switching, or continuing the same regimen with frequent viral load monitoring	Not recommended	Not recommended	Not recommended
PIs Used in combination with a dual-NRTI backbone[c]					
ATV/r	Preferred	Continue	Preferred	Preferred	Preferred
DRV/r	Preferred	Continue	Preferred	Preferred	Preferred
LPV/r	Alternative	Continue	Alternative	Alternative	Alternative
ATV/c[e]	Not recommended	Consider altering the regimen, or continuing the same regimen with frequent viral load monitoring	Not recommended	Not recommended	Not recommended
DRV/c[e]	Not recommended	Consider altering the regimen, or continuing the same regimen with frequent viral load monitoring	Not recommended	Not recommended	Not recommended
NNRTIs Used in combination with a dual-NRTI backbone[c]					
EFV	Alternative	Continue	Alternative	Alternative	Alternative
RPV[f]	Alternative	Continue	Alternative	Alternative	Alternative
DOR	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
ETR[g]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances

Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (page 2 of 4)

ART Regimen Component	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[a]	New ARV Regimen for Pregnant Women Whose Current Regimen is Not Well Tolerated and/or is Not Fully Suppressive[a]	ART for Nonpregnant Women Who Are Trying to Conceive[a,b]
NNRTIs Used in combination with a dual-NRTI backbone[c]					
NVP[g]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
NRTIs[c,h]					
ABC[i]	Preferred	Continue	Preferred	Preferred	Preferred
FTC	Preferred	Continue	Preferred	Preferred	Preferred
3TC	Preferred	Continue	Preferred	Preferred	Preferred
TDF	Preferred	Continue	Preferred	Preferred	Preferred
ZDV	Alternative	Continue	Alternative	Alternative	Alternative
TAF[j]	Insufficient data	Continue	Insufficient data	Insufficient data	Insufficient data
Entry and Fusion Inhibitors					
IBA	Insufficient data	Insufficient data	Insufficient data	Insufficient data	Insufficient data
MVC[g]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
T-20[g]	Not recommended	Continue	Not recommended, except in special circumstances	Not recommended, except in special circumstances	Not recommended, except in special circumstances
FDC Regimens[e,h] The individual drug component that is most responsible for the overall recommendation is indicated in parentheses.					
ABC/DTG/3TC[d,i]	Preferred	Continue	Preferred	Preferred	Alternative (DTG)
EFV/FTC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
EFV/3TC/TDF	Alternative (EFV)	Continue	Alternative (EFV)	Alternative (EFV)	Alternative (EFV)
FTC/RPV/TDF[f]	Alternative (RPV)	Continue (RPV)	Alternative (RPV)	Alternative (RPV)	Alternative (RPV)
BIC/FTC/TAF	Insufficient data (BIC, TAF)	Insufficient data (BIC)	Insufficient data (BIC, TAF)	Insufficient data (BIC, TAF)	Insufficient data (BIC, TAF)
DOR/3TC/TDF	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)	Insufficient data (DOR)

Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive (page 3 of 4)

ART Regimen Component	ART for Pregnant Women Who Have Never Received ARV Drugs and Who Are Initiating ART for the First Time	Continuing ART for Women Who Become Pregnant on a Fully Suppressive, Well-Tolerated Regimen	ART for Pregnant Women Who Have Received ARV Drugs in the Past and Who Are Restarting ART[a]	New ARV Regimen for Pregnant Women Whose Current Regimen is Not Well Tolerated and/or is Not Fully Suppressive[a]	ART for Nonpregnant Women Who Are Trying to Conceive[a,b]
FDC Regimens[e,h] The individual drug component that is most responsible for the overall recommendation is indicated in parentheses.					
FTC/RPV/TAF	Insufficient data (TAF[j])	Continue (RPV[f], TAF[j]) or consider switching to FTC/RPV/TDF	Insufficient data (TAF[j])	Insufficient data (TAF[j])	Insufficient data (TAF[j])
EVG/c/FTC/TDF[e]	Not recommended (EVG/c)	Consider switching, or continuing the same regimen with frequent viral load monitoring (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)
EVG/c/FTC/TAF[e]	Not recommended (EVG/c)	Consider switching, or continuing the same regimen with frequent viral load monitoring (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)	Not recommended (EVG/c)
DRV/c/FTC/TAF[e]	Not recommended (DRV/c)	Consider switching, or continuing the same regimen with frequent viral load monitoring (DRV/c)	Not recommended (DRV/c)	Not recommended (DRV/c)	Not recommended (DRV/c)
DTG/3TC As a complete regimen[k]	Not recommended	Not recommended; switch, or add additional agents	Not recommended	Not recommended	Not recommended
DTG/RPV As a complete regimen[k]	Not recommended	Not recommended; switch, or add additional agents[f]	Not recommended	Not recommended	Not recommended

[a] **Do not initiate** ARV regimens with components that have documented resistance or suspected resistance based on prior ARV exposure.

[b] This guidance is intended for women who are trying to conceive. These recommendations are not intended for all women with HIV who might become pregnant.

[c] ABC plus 3TC, TDF plus FTC, and TDF plus 3TC are *Preferred* dual-NRTI backbones, and ZDV plus 3TC is an *Alternative* dual-NRTI backbone for ARV regimens.

[d] The decision to designate DTG as a *Preferred* ARV drug for therapy in pregnant women, irrespective of trimester, was based on several factors. First, DTG is associated with higher rates of virologic suppression, faster rates of viral load decline, and a higher genetic barrier to drug resistance than other *Preferred* and *Alternative* agents. Second, a recent study that evaluated a large number of pregnancies has shown that the risk of NTDs is lower than previously reported in preliminary data. This risk is also largely limited to a short period of time (before 6 weeks post-last menstrual period). A very small minority of women with HIV initiate their first ARV regimen during this period of time. Some Panel members would avoid using DTG in women who are initiating ART before 6 weeks of gestation. After this time, any additional risk of NTDs due to DTG is minimal. Third, data are extremely limited on the risks that are associated with using other *Preferred* and *Alternative* ARV drugs preconception or in very early pregnancy; this lack of data does not indicate either the presence or absence of risk when using alternatives to DTG. DTG is recommended as an Alternative agent for people trying to conceive, as these patients have more time to achieve virologic suppression on regimens that do not contain DTG. For additional information see Teratogenicity, Updated Guidance About the Use of Dolutegravir in Pregnancy in Recommendations for the Use of Antiretroviral Drugs in Pregnancy, and Appendix D: Dolutegravir Counseling Guide for Health Care Providers.

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[e] DRV/c, EVG/c, and ATV/c **are not recommended** for use in pregnancy due to PK changes that pose a risk for low drug levels and viral rebound in the second and third trimesters. However, in cases where virologically suppressed pregnant women present to care on regimens that include these drugs, clinicians can consider continuing the use of these drug combinations with frequent viral load monitoring. If there are concerns about switching, see Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy.

[f] Although PK data indicate that RPV plasma concentration is reduced during the second and third trimester, the reduction is less than the reductions seen with use of EVG/c or DRV/c. Higher-than-standard doses of RPV have not been studied, so there are insufficient data to recommend a dose change in pregnancy. With standard dosing, viral load should be monitored more frequently.

[g] Although these drugs are not recommended for initial treatment in ART-naive pregnant women, there may be special circumstances in which ART-experienced women may need to continue or initiate ETR, NVP, MVC, and T-20 in order to maintain or achieve viral suppression. There are limited safety and efficacy data about the use of ETR, MVC, and T-20 in pregnancy. NVP is not recommended for ART-naive women because it has a greater potential for adverse events than other NNRTIs, complex lead-in dosing, and a low barrier to resistance; however, if a pregnant woman presents to care on a well-tolerated, NVP-containing regimen, it is likely that NVP will be safe and effective during pregnancy. See Table 4 and Nevirapine for more information.

[h] When using FDC tablets, refer to Table 8 and the drug sections in Appendix B for information about the dosing and safety of individual components of the FDC tablet during pregnancy.

[i] Testing for HLA-B*5701 identifies patients who are at risk of developing hypersensitivity reactions while taking ABC; testing should be performed and a patient should be documented as negative before initiating ABC.

[j] Available data about the use of TAF in pregnancy support continuing it in pregnant women who are virally suppressed, although data are insufficient to recommend it when initiating ART in pregnancy.

[k] Two-drug ARV regimens **are not recommended** for use in pregnancy.

The following drugs and drug combinations (that are not listed above) should not be used during pregnancy; if a woman becomes pregnant while taking any of these medications, she should switch to a recommended regimen: d4T, ddI, FPV, FPV/r, IDV, IDV/r, NFV, RTV (as the sole PI), SQV, SQV/r, TPV, TPV/r, or a three-NRTI ARV regimen (e.g., ABC/ZDV/3TC). See Archived Drugs in the Perinatal Guidelines and What Not to Use in the Adult and Adolescent Antiretroviral Guidelines for individual ARV drugs, ARV combinations, and ARV regimens that are not recommended or that should not be used in adults. Refer to the table above and Table 4 for ARV regimens that are recommended for use in pregnancy.

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; d4T = stavudine; ddI = didanosine; DOR = doravirine; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG/c = elvitegravir/cobicistat; FDC = fixed-dose combination; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; IBA =ibalizumab; IDV = indinavir; IDV/r = indinavir/ritonavir; INSTI = integrase strand transfer inhibitor; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQV = saquinavir; SQV/r = saquinavir/ritonavir; T-20 = enfuvirtide; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; ZDV = zidovudine